Complete Summary

GUIDELINE TITLE

Prevention or delay of type 2 diabetes.

BIBLIOGRAPHIC SOURCE(S)

Sherwin RS, Anderson RM, Buse JB, Chin MH, Eddy D, Fradkin J, Ganiats TG, Ginsberg HN, Kahn R, Nwankwo R, Rewers M, Schlessinger L, Stern M, Vinicor F, Zinman B. Prevention or delay of type 2 diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S47-54. [60 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Pre-diabetes (impaired fasting glucose or impaired glucose tolerance)

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To discuss approaches to and provide recommendations for the prevention of type 2 diabetes

TARGET POPULATION

Individuals with risk factors for developing diabetes, including:

- Age $\geq$45 years
- Overweight (body mass index [BMI] $\geq$25 kg/m^2) (Note: This may not be correct for all ethnic groups.)
- First-degree relative with diabetes
- Habitual physical inactivity
- Member of a high-risk ethnic population (e.g., African-American, Latino, Native American, Asian-American, Pacific Islander)
- Previously identified pre-diabetes (impaired fasting glucose or impaired glucose tolerance)
- History of gestational diabetes mellitus or delivery of a baby weighing >9 lbs
- Hypertensive ($\geq$140/90 mmHg)
- High-density lipoprotein cholesterol level $\leq$35 mg/dl (0.90 mmol/l) and/or a triglyceride level $\geq$250 mg/dl (2.82 mmol/l)
- Polycystic ovary syndrome
- History of vascular disease

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Identify potential candidates according to risk factors
2. Laboratory testing
    - Fasting plasma glucose
    - 2-hour oral glucose tolerance test

Prevention

1. Lifestyle modification (weight loss, physical activity)
2. Treatment for other cardiovascular risk factors including tobacco use, hypertension, and dyslipidemia
3. Drug therapy (discussed but not recommended)

MAJOR OUTCOMES CONSIDERED

- Glucose levels
- Incidence of diabetes following lifestyle interventions and/or drug therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see table below). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they

are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

American Diabetes Association's evidence grading system for clinical practice recommendations:

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved by the American Diabetes Association Professional Practice Committee and by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system (A-C, E) is defined at the end of the "Major Recommendations" field.

Synopsis of Recommendations to Prevent or Delay Diabetes

- Individuals at high risk for developing diabetes need to become aware of the benefits of modest weight loss and participating in regular physical activity. (A)
- Based on current screening guidelines for diabetes, men and women $\geq$45 years of age, particularly those with a body mass index (BMI) $\geq$25 kg/m^2*, are candidates for screening to detect pre-diabetes (impaired fasting glucose [IFG] or impaired glucose tolerance [IGT]). Screening should be considered in younger individuals with a BMI $\geq$25 kg/m^2* who have additional risk factors (see Table 3 in original guideline document). (B)
- In individuals with normoglycemia, rescreening at 3-year intervals is reasonable. (C)
- Screening should be carried out only as part of a health care office visit. Either a fasting plasma glucose test or 2-hour oral glucose tolerance test (75-g glucose load) is appropriate, and positive test results should be confirmed on another day. (B)
- Patients with pre-diabetes (IFG or IGT) should be given counseling on weight loss as well as instruction for increasing physical activity. (A)
- Follow-up counseling appears important for success. (B)
- Monitoring for the development of diabetes should be performed every 1 to 2 years. (E)
- Close attention should be given to, and appropriate treatment given for, other cardiovascular disease risk factors (e.g., tobacco use, hypertension, dyslipidemia). (A)
- Drug therapy should not be routinely used to prevent diabetes until more information is known about its cost-effectiveness. (E)

*This BMI may not be correct for all ethnic groups.

Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

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- Evidence from a well-conducted multicenter trial
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- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted prospective cohort study
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Supportive evidence from a well-conducted case-control study

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- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Current knowledge of the early stages of hyperglycemia that portend the diagnosis of diabetes and the recent success of major intervention trials clearly show that individuals at high risk can be identified and diabetes delayed, if not prevented. The cost-effectiveness of intervention strategies is unclear, but the huge burden resulting from the complications of diabetes and the potential ancillary benefits of some of the interventions suggest that an effort to prevent diabetes may be worthwhile.

POTENTIAL HARMS

The cost of identifying individuals with pre-diabetes (impaired fasting glucose or impaired glucose tolerance) and then intervening to prevent diabetes has implications other than financial. Individuals can react negatively to whatever label they are given, and some may be discriminated against in the workplace or by insurers. Any intervention can, of course, promote anxiety and be socially disruptive. Finally, hazards resulting from the use of medications are always possible.

QUALIFYING STATEMENTS

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Evidence is only one component of decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies such as the one adapted by the American Diabetes Association may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jan (republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

The guideline was prepared by a workgroup sponsored by the American Diabetes Association and the National Institute of Diabetes, Digestive and Kidney Diseases of the National Institutes of Health.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The workgroup consisted of Robert S. Sherwin, MD (Chair), Robert M. Anderson, EdD, John B. Buse, MD, PhD, Marshall H. Chin, MD, MPH, David Eddy, MD, PhD, Judith Fradkin, MD, Theodore G. Ganiats, MD, Henry N. Ginsberg, MD, Richard Kahn, PhD, Robin Nwankwo, RD, MPH, MS, Marion Rewers, MD, MPH, Leonard Schlessinger, PhD, Michael Stern, MD, Frank Vinicor, MD, MPH, and Bernard Zinman, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

American Diabetes Association (ADA) position statements are reissued annually.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 29, 2003. The summary was updated by ECRI on March 23, 2004.

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